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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,388	02/05/2004	Horst Georg Zerbe	2004-0189	3058

7590 08/22/2007  
Michael R. Davis  
WENDEROTH, LIND & PONACK  
Suite 800  
2033 "K" Street N.W.  
Washington, DC 20006-1021

EXAMINER
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ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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08/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/771,388	Applicant(s) ZERBE ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-31 and 33-56 is/are pending in the application.
- 4a) Of the above claim(s) 41-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-31, 33-40 and 52-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

This office action is in response to the Request for Continued Examination filed June 5, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)**

1) Claims 10-11, 18-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al. (US 5,456,745).

Roreger et al. disclose hydrophilic gel films that may be used to deliver active substances via the mucous membrane (col. 10, lines 31-35). The films comprise water-soluble polymers such as carboxymethylcelluloses, hydroxyethyl cellulose, hydroxypropyl cellulose and karaya gum, which comprise 0.5 to 30% of the films. The films may comprise one or more active substances, which comprises 0 to 50% of the films (col. 1, lines 19-55). The substances include systemic actives such as nicotine (col. 11, lines 20-22) and essential oils such as peppermint (col. 12, line 1). Moisturizers such as glycerol and sorbitol (a sweetener) are included in the films, which comprise 0.1% to 20% of the films. Auxiliaries comprise 0 to 75% of the films. Surfactants such as polyethylene glycol fatty acid ester, polyethylene glycol fatty alcohol ether, or polyethylene glycol-sorbitan-fatty acid esters and/or softeners, such as glycerol diacetate, which is a surfactant, may be included in the films (col. 3, line 53 to col. 4, line

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7). When a softener and a surfactant are used, the combination may be considered two surfactants. Other auxiliaries include thickeners such as polyvinyl pyrrolidone; tackifiers such as natural gums, sugar and honey (col. 7, lines 55-61); penetration accelerators such as fatty acid salts of multivalent metals, betaine and alkyl sulphates; preserving agents such as propylene glycol; and cross-linking agents such as multivalent acids including tartrate and citrate ions. The films are dried to their desired thickness (col. 8, lines 35-40).

The reference differs from the instant claims insofar as it does not disclose an example with all of the components.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used the auxiliary agents such as surfactants, softeners, cross-linking agents and tackifiers or mixtures of active agents such as nicotine and peppermint oil in the films of the reference motivated by the desire to obtain their known function such as the surfactants' solubilizing function, the honey's tackifier function (also a sweetener), the peppermint oil for its therapeutic function (also a flavoring) and nicotine for its therapeutic function as disclosed by the reference and supported by case law.

2) Claims 12-17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al. (US 5,456,745) in view of Inoue et al. (US 4,772,470).

The primary reference is discussed above. The reference differs from the instant claims insofar as it does not disclose the thickness of the film or that a coloring agent may be used in the films.

Inoue et al. discloses oral bandages and oral preparations. The preparations comprise an adhesive film comprising a drug. The thickness of the resulting film is preferably adjusted to a range of from 5 to 100 micrometers by controlling the amount of the casting solution, and the like. If a film thickness is less than 5 micrometers it is difficult to obtain sufficient adhesion. A film having a thickness exceeding 100 micrometers tends to produce a feeling foreign to the mouth and to impair softness of the film (col. 8, lines 11-17). Other additives are added to the compositions such as flavoring and coloring matter (col. 10, lines 5-10). The reference differs from the instant claims insofar as it does not disclose nicotine in the compositions.

It would have been obvious to one of ordinary skill in the art to have adjusted the thickness parameters of the films to between 5 to 100 micrometers in the primary reference motivated by the desire to obtain sufficient adhesion while not producing a film that has a foreign feeling in the mouth, as disclosed by the secondary reference. (Note that this is the same reason preferred by Applicant. See Remarks of the Amendment filed October 16, 2006, page 11, lines 5-6 from the bottom.)

**Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)**

1) Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Acharya (US 5,686,094). The rejection is maintained.

Applicant has not supplied an argument or has not made reference to the previously filed remarks in the After final amendment filed May 4, 2007 in view of the Examiner's remarks in the Advisory Action, therefore the rejection is maintained.

2) Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Story et al. (US 4,944,949). The rejection is maintained.

Applicant has not supplied an argument or has not made reference to the previously filed remarks in the After final amendment filed May 4, 2007 in view of the Examiner's remarks in the Advisory Action, therefore the rejection is maintained.

3) Claims 28-29, 31, 33-35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Inoue et al. (US 4,772,470). The rejection is maintained and further applied to claims 53-56.

Applicant has not supplied an argument or has not made reference to the previously filed remarks in the After final amendment filed May 4, 2007 in view of the Examiner's remarks in the Advisory Action, therefore the rejection is maintained.

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4) Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Inoue et al. (US 4,772,470) as applied to claims 28-29, 31, 33-35, and 38-40 above, and further in view of Stanley et al. (US 5,783,207). The rejection is maintained and applied to new claims 52.

Applicant has not supplied an argument or has not made reference to the previously filed remarks in the After final amendment filed May 4, 2007 in view of the Examiner's remarks in the Advisory Action, therefore the rejection is maintained.

5) Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Inoue et al. (US 4,772,470) as applied to claims 28-29, 31, 33-35, and 38-40 above, and further in view of Story et al. (US 4,944,949). The rejection is maintained.

Applicant has not supplied an argument or has not made reference to the previously filed remarks in the After final amendment filed May 4, 2007 in view of the Examiner's remarks in the Advisory Action, therefore the rejection is maintained.

Claims 10-31, 33-40 and 52-56 are rejected.

Claim 32 is cancelled.


No claims allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Lezah Roberts  
Patent Examiner  
Art Unit 1614

  
Frederick Krass  
Primary Examiner  
Art Unit 1614